QA: QA

U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT M&O-ARP-00-13

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR

AT

LAS VEGAS, NEVADA

JULY 10-19, 2000

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1.0 EXECUTIVE SUMMARY

As a result of performance-based Quality Assurance (QA) audit M&O-ARP-00-13 of the Total System Performance Assessment - Site Recommendation (TSPA-SR), the audit team determined that the Civilian Radioactive Waste Management Systems Management and Operating Contractor (CRWMS M&O) is implementing adequate process controls for the selected products evaluated during the audit. However, further evaluation is needed before an objective assessment can be made regarding the adequacy and effectiveness of the TSPA-SR process. The audit was performed in accordance with the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD) document DOE/RW-0333P, Revision 10, and applicable QA procedures.

Based on reviews of documentation and personnel interviews, it was determined that the TSPA-SR products are, for the most part, being developed in accordance with QA program requirements. The audit team identified conditions adverse to quality which were documented as deficiency reports (DR) in the areas of assessing the impact of unqualified/unconfirmed data on the TSPA-SR and supporting analyses/models (DR LVMO-00-D-117); transparency of decisions made regarding uncertainty/variability values, assumptions, and alternative models (DR LVMO-00-D-118); model validation (confidence building) (DR LVMO-00-D-119); submittal of information to the Model Warehouse (a Technical Data Management System [TDMS] module) (DR LVMO-00-D-120); and adhering to planning documents and/or revising planning documents when substantive changes occur (DR LVMO-00-D-121). The impact of these deficiencies is yet to be determined; however, based on the audit results, transparency must be enhanced and an integrated approach implemented that ensures defensibility of decisions made at each stage of the entire TSPA-SR process.

Note that the CRWMS M&O Performance Assessment (PA) organization relies upon input from several sources, and is not organizationally responsible for the quality of all TSPA-SR inputs. Therefore, this audit was of the TSPA-SR process and not of the PA organization.

Section 5.0 documents the summary of audit results, which includes a technical assessment of the identification, selection and treatment of Features, Events and Processes (FEP), and an assessment of selected analyses and models that support the TSPA-SR model. In addition, six recommendations are provided for management consideration and response in Section 6.0 of this report.

A technical issue regarding use of Gaussian Variance Partitioning (GVP) for Waste Package Degradation Modeling (WAPDEG) was identified and discussed during the audit. This issue, which was not considered a process deficiency, will be transmitted by the Yucca Mountain Site Characterization Office (YMSCO) to the CRWMS M&O for evaluation and response.

2.0 SCOPE

The audit was conducted to evaluate the quality of the TSPA-SR inputs (analyses, models, data, and software), the adequacy of the TSPA-SR model, and the effectiveness of the TSPA-SR approach.

Based on the approved audit plan, the OQA evaluation of the TSPA-SR will take place in two phases. Phase 1, which began with this audit, is to address identification/screening of FEPs; development/analysis of scenarios; traceability/transparency of assumptions, uncertainties, rationale, and data; impact reviews/analyses; software qualification; model abstraction; and the performance/documentation of the TSPA-SR model. The Phase 2 audit, which is tentatively scheduled for the first quarter of fiscal year 2001, is to address incorporation of design changes, performance of calculations, sensitivity analysis, evaluation of parameter ranges and uncertainties, transparency, and defensibility of TSPA-SR results/conclusions.

Note that two activities planned for audit during Phase 1 could not be assessed, i.e., development/analysis of scenarios and performance/documentation of the TSPA-SR model. The compressed TSPA-SR schedule resulted in a decision to incorporate the scenario development into the TSPA-SR, Rev. 00, technical report, which will be evaluated during the Phase 2 audit. The TSPA-SR model report was behind schedule and only in draft at the time of the audit. The draft was evaluated during the audit, which provided an opportunity for the audit team to suggest enhancements; however, the audit objective to evaluate the adequacy of the TSPA-SR model could not be performed as planned.

The Phase 1 approach was to select four of the 26 abstraction-level Analysis and Model Reports (AMR), which are the direct inputs to the TSPA-SR. The objective was to evaluate AMR inputs for traceability and transparency of quality status; to evaluate the abstraction process for transparency of decisions made regarding uncertainties, assumptions, and alternative models; and to evaluate the incorporation of the model abstractions into the TSPA-SR model. The selected abstraction-level AMRs and the TSPA-SR Model report are as follows:

- ANL-EBS-PA-000001, “WAPDEG Analysis of Waste Package and Drip Shield Degradation,” Rev. 00 (AMR W0050)
- ANL-WIS-MD-000010, “Summary of Dissolved Concentration Limits,” Rev. 00 (AMR F0095)
- ANL-NBS-MD-000005, “Abstraction of Drift Seepage,” Rev. 00 (AMR U0120)
- ANL-NBS-MD-000007, “Abstraction of BDCF Distribution for Irrigation Period,” Rev. 00 (AMR B0075)
- MDL-WIS-PA-000002, “Total System Performance Assessment (TSPA) Model for Site Recommendation” (draft TSPA-SR model report)

In addition to evaluating the model abstraction process, the audit scope included an evaluation of the FEPs identification/screening process. Five FEPs-related AMRs were selected for evaluation as follows:

- ANL-NBS-MD-000001, “Features, Events, and Process in UZ Flow and Transport," Rev. 00 (AMR U0170)
- ANL-EBS-PA-000002, "FEPS Screening of Processes and Issues in Drip Shield and Waste Package Degradation,” Rev. 00 (AMR W0055)
- ANL-WIS-MD-000008, "Clad Degradation - FEPs Screening Arguments,” Rev. 00 (AMR F0050)
- ANL-WIS-MD-000009, "Miscellaneous Waste-Form FEPs,” Rev. 00 (AMR-F0185)
- ANL-MGR-MD-000011, "Evaluation of the Applicability of Biosphere-Related Features, Events, and Processes (FEP)," Rev. 00 (AMR B0000)

Note that the selected FEPs AMRs coincide with the subject areas of the selected abstraction-level AMRs identified above, i.e., Waste Package Degradation, Waste Form Degradation, Unsaturated Zone Flow and Transport, and Biosphere.

PROCESS/ACTIVITY/END-PRODUCT

1. Satisfactory implementation of the critical process steps;
2. Use of trained and qualified personnel working effectively;
3. Documentation that substantiates the quality of the product;
4. Acceptable results and adequate end-product; and
5. Effectiveness of corrective action.

The following critical process steps were considered during the evaluation of the selected AMRs.

TSPA-SR Goals & Objectives
- Overall TSPA-SR Approach
- Acceptance Criteria
- Planning
- Milestones

TSPA-SR Technical/Regulatory Issues
- Impact Evaluations/Analyses
- Technical Review
- NRC Key Technical Issues/Subissues
- Peer Review Panel Recommendation Follow-up
- Repository Safety Strategy

TSPA-SR Inputs
- Input Requests
- Data Qualification/Acceptance
- Expert Judgment/Elicitation
- Assumptions
- Software Qualification

TSPA-SR Tasks
- Identify/Screen FEPs
- Develop/Screen Scenarios
- Develop Models
- Estimate Parameter Ranges and Uncertainty
- Perform Calculations
- Interpret/Document Results

TSPA-SR Outputs
- Comparisons with Regulatory Requirements
- Quantification of Output Uncertainty

TECHNICAL AREAS

The audit included a technical evaluation of process effectiveness and product acceptability. Details of the technical evaluation are included in Section 5.4 of this report.

3.0 AUDIT TEAM MEMBERS/OBSERVERS

The following is a list of audit team members:

Kristi A. Hodges, Audit Team Leader, OQA/QATSS
James Blaylock, Auditor, OQA
Michael J. Eshleman, Auditor, Management Technical Support (MTS)
F. Harvey Dove, Technical Specialist, OQA/QATSS
W. Mark Nutt, Technical Specialist, MTS
Richard E. Powe, Auditor, OQA/QATSS
James V. Voigt, Auditor, OQA/QATSS
Alf Wikjord, Technical Specialist, Atomic Energy of Canada Limited
Frank M. Wong, Technical Specialist, MTS

There were seven observers present during the audit:

Robert Brient, Center for Nuclear Waste Regulatory Analyses (CNWRA), San Antonio, Texas
Richard Codell, U.S. Nuclear Regulatory Commission (NRC), White Flint, Maryland
David Esh, U.S. NRC, White Flint, Maryland
Tim Kobetz, U.S. NRC, White Flint, Maryland
Sitikanta Mohanty, CNWRA, San Antonio, Texas
Osvaldo Pensado, CNWRA, San Antonio, Texas
Michael Smith, CNWRA, San Antonio, Texas

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was conducted at the YMSCO in Las Vegas, Nevada, on July 10, 2000. Daily debriefing and coordination meetings were held with the CRWMS M&O management and staff, and daily audit team meetings were held to discuss audit status. The audit was concluded with a post-audit meeting held on July 19, 2000, at the CRWMS M&O offices in Las Vegas, Nevada.

Personnel contacted during the audit, including those who attended pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that further evaluation during Phase 2 is needed before an objective assessment can be made regarding the adequacy and effectiveness of the TSPA-SR process. The abstraction AMRs evaluated were, for the most part, considered technically sound; however, process weaknesses in areas of model validation and transparency appear to undermine the defensibility of the TSPA-SR products.

Although significant improvement is noted in the consistency of AMR format and clarity of content, weaknesses remain in the documentation of model validation (confidence building). Some AMR authors have done an exceptional job in implementing Administrative Procedure (AP)-3.10Q, "Analyses and Models," Rev. 2, which was revised to address model validation issues and concerns. However, other AMR authors are struggling with these requirements, as evidenced by the absence of validation criteria and results from their analyses/models. It appears that a more rigorous approach to validation is needed, one that documents validation criteria and methods within a planning document

that is subject to review/approval. There are models that are understandably difficult to validate; however, alternative approaches per AP-3.10Q, Revision 2, ICN 2, paragraph 5.3c, may be required in order to defend the model/analysis as appropriate and adequate for its intended use. Such alternative approaches must be planned, executed, and documented in sufficient time to support the TSPA milestones (See Recommendation #1).

Transparent documentation is critical to defensibility and acceptability of the TSPA-SR. The OCRWM QARD requires transparent documentation; however, transparency is not defined in the QARD, and a process to achieve transparency has not been established in project procedures. Based on the audit results, transparency of decisions made regarding uncertainty/variability values, assumptions, and alternative models; and transparency of NRC Issue Resolution Status Reports (IRSR) resolutions must be strengthened before the TSPA-SR process can be deemed adequate and effective.

Although the decisions made may be defensible, transparent documentation can only strengthen our technical argument and minimize or eliminate the need to determine why former decisions were made. It will reduce the need for an AMR author (or representative) to retrace steps to establish why one approach was taken and another excluded. There is reasonable transparency within the process-level AMRs; however, the abstraction-level AMR authors have assumed no responsibility for integrating the various uncertainty/variability values, assumptions, and alternative models that are contained within the process-level AMRs. Project procedures do not specify such integration; therefore, the evidence that all applicable information within a family of AMRs was considered at the abstraction-level is not readily apparent.

Five deficiency documents were issued as a result of the audit, which, if addressed and corrected, will strengthen the defensibility of the TSPA-SR final products. Descriptions of the deficiencies are contained in Section 5.5 of this report. Six recommendations are provided for management consideration and response in Section 6.0 of this report.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions as a result of the audit.

5.3 QA Program Audit Activities

Attachment 2, “Summary Table of Audit Results,” provides results for each critical process step evaluated. Details of the audit, including the objective

evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA Record.

5.4 Technical Audit Activities

TSPA-SR Goals & Objectives

Overall TSPA-SR Approach/Acceptance Criteria: The TSPA-SR Methods and Assumptions document (TDR-MGR-MD-000001, Rev. 00, ICN 02) establishes the TSPA-SR approach. This document is intended to include the goals, objectives, scope, methods, approach and assumptions to be used in the development of the TSPA-SR. It is also to reflect the acceptance criteria for the NRC Total System Performance Assessment and Integration (TSPAI) IRSR. The TSPAI was revised in January 2000 (Rev. 2); however, the Methods and Assumptions document has yet to be updated to reflect the revised TSPAI criteria (See recommendation # 2).

There is a perception that AMRs feed Process Model Reports (PMR) that feed the TSPA-SR model. In reality, the process-level AMRs feed abstraction-level AMRs, which feed the TSPA-SR model. And, the PMRs remain external to the TSPA-SR model. A source of this perception is the Methods and Assumptions document itself, as it indicates the AMR/PMR/TSPA-SR hierarchy. Based on discussions during the audit, that hierarchy was initially conceived, but subsequently disregarded; however, the Methods and Assumptions document was not updated to reflect the actual hierarchy (See Recommendation # 2).

Planning: The TSPA-SR Methods and Assumptions document is the foundational TSPA-SR planning document, as it establishes the overall TSPA-SR approach. However, as noted above, it is not current with NRC TSPAI criteria. Likewise, TSPA-SR plans that respond to project planning procedures were assessed as fragmented and, in some cases, out of date. DR LVMO-00-D-121 documents that plans were not followed and/or revised when substantive changes occurred. Changes to the project planning process were established in AP-2.21Q, "Quality Determinations and Planning for Scientific, Engineering, and Regulatory Compliance Activities," Revision 0, which should result in improved planning documents.

Milestones: The compressed schedule for completing TSPA-SR deliverables was highlighted throughout the audit. Delays in issuance of the process-level AMRs resulted in subsequent delays in development of the abstraction-level AMRs and, therefore, delays in development of the TSPA-SR model report. The phrase "developing in parallel" has been used to describe the state of several AMRs developing concurrently, although the output of one AMR is needed as an input to another. The PA organization has worked to meet both quality and schedule

demands; however, concerns regarding the qualification status of data and software, technical review, and deferring issues to future AMR revisions continue to be raised. In addition, previously established milestones, e.g., sensitivity calculations and scenario development/screening, have been deferred to the TSPA-SR, Rev. 00, technical report. Folding previous milestones into the technical report may be advantageous from a schedule perspective; however, it does not come without reservation. If the technical report is to document new information that is not found in an AMR or calculation document that has undergone critical evaluation, increased preparation/review time for the technical report will inevitably be needed. The overall concern is that quality might be compromised in order to meet schedule demands. Further evaluation of this concern will take place during the Phase 2 audit.

TSPA-SR Technical/Regulatory Issues

Impact Evaluations/Analyses: No deficiencies were noted in performance of impact reviews in accordance with AP-3.17Q, "Impact Reviews"; however, there was insufficient implementation to evaluate the effectiveness of the process. Significant design changes related to removal of backfill from the repository design will result in several AMR revisions; therefore, this process will be further evaluated as part of the TSPA-SR Phase 2 audit.

Technical Review: The audit results reaffirmed that the AP-3.10Q checking process is working effectively; however, one deficiency (DR LVMO-00-D-121) was identified regarding author/checker responsibilities for ensuring that technical products are consistent with planning documents. Review records were evaluated and determined effective in demonstrating a comprehensive technical review. Note that AP-2.14Q, "Review of Technical Products" has not been implemented for some AMRs, since AP-3.10Q specifies that the AP-2.14Q review is applicable when an analysis or model impacts a functional discipline or organization other than the originating organization. For example, an AP-2.14Q review was not performed on the WAPDEG abstraction (AMR W0050), since the product was developed by the PA organization for the PA organization. This is not a procedure violation; however, it is perceived as a process weakness, as the abstraction-level AMRs generated by the PA organization do not receive the benefit of external review/comment (See recommendation #3).

NRC Key Technical Issues/Subissues: As stated earlier, the TSPA-SR Methods and Assumptions document, which establishes the TSPA-SR approach, has not been revised to address the NRC TSPAI IRSR, Rev. 2. Likewise, AMRs, e.g., WAPDEG abstraction, are not responsive to the current NRC acceptance criteria. Although future AMR revisions are expected to respond to NRC acceptance criteria, few current AMRs (Rev. 00) address relevant IRSRs with the intent of

resolving an open key technical issue/subissue. Refer to DR LVMO-00-D-118 for issues related to integration/responsiveness to IRSR acceptance criteria.

Note that the AMR to TSPA-SR model relationship does not place PMRs in a position to address relevant TSPAI IRSR criteria. It was stated during the audit that the TSPA-SR technical report will address IRSRs; however, it is not apparent how the report will derive conclusions from AMRs that were, for the most part, developed by authors who assumed no responsibility for addressing IRSR criteria. It appears that decisions were made to address IRSRs outside of the AMRs; however, it also appears that the misunderstanding in where PMRs fell in the TSPA-SR hierarchy has weakened the transparency of IRSR resolutions.

Peer Review Panel Follow-up: It is not readily apparent how or where the commitments made in the formal responses to the TSPA-Viability Assessment (VA) peer review panel recommendations are addressed within AMRs, e.g., the WAPDEG abstraction. DR LVMO-00-D-121 addresses deviation from the WAPDEG planning document in the area of TSPA-VA peer review recommendations (See Recommendation #4).

Repository Safety Strategy (RSS): At the time of the audit, the RSS document was in revision. The proposed Revision 4 will add two new Principle Factors related to Disruptive Events (Probability of Igneous Activity and Repository Response to Igneous Intrusion). Based on discussion, the number of data sets requiring qualification (or AP-3.15Q confirmation) are not expected to be significant.

TSPA-SR Inputs

Input Requests: Based on the audit results, AP-3.14Q, "Input Requests," is being effectively implemented. No deficiencies or concerns were identified during the audit.

Data Qualification/Accepted Data/Data Status: No data qualification efforts per AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," were associated with Data Tracking Numbers (DTN) that supported the selected AMRs. The data confirmation process per AP-3.15Q, "Managing Technical Product Inputs," continues to be implemented for DTNs that were previously qualified, but require confirmation based on issues related to Corrective Action Requests (CAR) LVMO-98-C-002 and CAR LVMO-99-C-001. No additional deficiencies related to traceability of data were identified during the audit; however, concerns regarding transparency of the status of inputs were discussed during the audit. An AP-3.15Q revision and Document Input Reference System (DIRS) database improvements are in

progress, which should provide a more complete and accurate status of AMR inputs.

Expert Judgment/Elicitation: Currently, the use of expert judgement/opinion is limited to the area of disruptive events through volcanism, which were not subject areas selected for this audit. However, overdependence on analytical values obtained from expert opinion rather than data collected via the quality program has been a previously noted concern. Enhanced transparency of TSPA-SR documents will highlight the minimal use of expert opinion, judgment and/or elicitation in the overall TSPA process.

Assumptions: Three issues regarding assumptions were identified during the audit. 1) Although assumptions are documented in the process-level AMRs, decisions regarding assumptions that were considered but not used in the abstraction-level AMRs are not clearly documented. This issue is included in DR LVMO-00-D-118, which also applies to uncertainty/variability values and alternative conceptual models. 2) Assumptions that support the FEPs screening arguments, notably in the Waste Package (WP) and Unsaturated Zone (UZ) AMRs, have yet to be verified To-Be-Verified (TBV) nor have TBV priorities been established. 3) Clarification is needed in the area of applying TBVs to assumptions, as some assumptions are given TBV numbers and others are not. There appears to be no clear understanding of the criteria used when determining whether a TBV number is needed and/or required (See Recommendation # 5).

Software Qualification: Software codes used for the selected abstraction AMRs and the TSPA-SR model were, with one exception (EQ3/6, Version 7.2b), in the qualification process. No deficiencies related to the qualification process were identified; however, the progress in qualifying software codes that support the TSPA-SR appears to be slow-paced. All software routines reviewed were documented within their respective AMRs. They had proper identification, which included name and version number of the routine and name and version number of the commercial software used to develop the routine. An issue that is related to previously issued DR LVMO-00-D-039 regarding classification of software codes as routines is documented in Section 5.5 of this report.

TSPA-SR Tasks

The technical evaluations below will address the process steps regarding FEPs identification/screening, model development, estimation of parameter ranges and uncertainty, and interpretation and documentation of results. The TSPA-SR products were evaluated to the extent possible. Scenario development/screening, sensitivity calculations and documentation of the TSPA-SR model and technical report will be evaluated (or further evaluated) during the TSPA-SR Phase 2 audit.

TSPA-SR Outputs

The technical evaluations below will address the process steps regarding comparisons with regulatory requirements and quantification of output uncertainty. The TSPA-SR products were evaluated to the extent possible; however, completed products will be evaluated as part of the TSPA-SR Phase 2 audit.

Technical Evaluation

Features, Events, and Processes:

The evaluation of the FEPs process concluded that the process is effective in demonstrating identification, selection and treatment of FEPs. Although the selected FEP AMRs were evaluated for clarity and comprehensiveness, much of the audit focus was on the adequacy of the FEP database. The FEP database, which is described in document TDR-WIS-MD-000003, Rev. 00, "The Development of Information Catalogued in Rev. 00 of the YMP FEP Database," has a logical hierarchical structure comprised of 4 layers, 12 categories and 135 headings. Each of the 1,797 FEPs has a unique number that identifies its layer, category, heading, primary classification, and secondary classification. Although the FEP database is relied upon for accurate and complete information, the FEP AMRs are the quality-affecting documents from which the information in the database is derived. To ensure the integrity of database entries, OCRWM QARD Supplement V controls have been applied to the transfer of electronic information from the FEP AMRs to the database. In addition, qualification of the database software application per OCRWM QARD Supplement I is under evaluation as a precursor to a fully qualified database status.

The following factors support the adequacy of the FEPs AMRs/Database.

- The iterative process to identify new FEPs builds confidence that few additional FEPs will be uncovered.
- The template structure helps ensure consistency, traceability, and transparency.
- There are well-defined criteria linked to regulatory requirements, probability, consequence, and site and design features.
- The FEP database is an excellent single-source entry and a user friendly tracking tool to a multitude of reports, analyses, technical bases arguments, and issues that cross-cut the AMRs and PMRs.
- Each primary FEP entry has a screening argument and a source citation.

The following factors may challenge the adequacy of the FEPs AMRs/Database.

- The FEP AMRs/database (Rev. 00) is rooted in the EDA2 design of the License Application Design Selection (LADS). New revisions/version are needed for the design specified for the TSPA-SR.
- The technical basis for the FEP screening is not necessarily found in the FEP AMRs; in some instances, it is found in higher-level documents. In those instances, the traceability of the screening arguments is more circuitous.
- TBV screening assumptions are not uniformly identified in the FEP database, e.g., TBVs associated with the WP FEP AMR are identified in the database; those associated with the UZ FEP AMR are not.
- The text associated with nuclear criticality is not included for 22 primary and 49 secondary FEPs.
- The categorization of primary FEPs, as both included and excluded rather than subdividing to ensure that they are fully included or excluded, may be challenged.

Analyses and Model Evaluations (Develop Models, Estimate Parameter Ranges and Uncertainty, Perform Calculations, and Interpret & Document Results):

ANL-EBS-PA-000001, Rev. 00, "WAPDEG Analysis of Waste Package and Drip Shield Degradation" (W0050)

The author of this model report incorporated the many process models that are used in the waste package degradation. WAPDEG captures all of the process models that affect waste package degradation for use with GoldSim, which is the software code that runs the TSPA-SR model. The WAPDEG AMR, Rev. 00, did not receive an AP-2.14Q review, which is discussed earlier in this report. At the time of the audit, a revision to the AMR (ICN 1) was being prepared. Several technical recommendations were directly submitted for inclusion to the ICN and will be revisited during the TSPA-SR Phase 2 audit.

The audit identified three deficient conditions that apply to the WAPDEG AMR. 1) The pertinent NRC IRSR (TSPAI and Container Life and Source Team [CLST]) Key Technical Issues/Subissues and TSPA-VA peer review panel recommendations for WAPDEG were not clearly addressed. This condition is documented in DR LVMO-00-D-121 (from a planning perspective) and DR LVMO-00-D-118 (from a transparency perspective). 2) There is no rationale or discussion as to why recommended uncertainty/variability values from process models, e.g., general corrosion, aging phase stability, and stress cracking corrosion, were not used and were substituted with other values in the WAPDEG analysis. This condition is documented in DR LVMO-00-D-118.

3) Although the WAPDEG AMR addresses model validation, it focuses on validation of the supporting software routines and not on validation of the WAPDEG model. Validation of this model is perceived as extremely complex and may require an alternative validation approach per AP-3.10Q, paragraph 5.3c, Revision 2, ICN 2. This condition is documented in DR LVMO-00-D-119.

Note that a technical issue regarding waste package degradation modeling and the use of the GVP technique as the method for capturing the fundamental processes related to general corrosion will be transmitted by YMSCO to the CRWMS M&O for evaluation and response.

ANL-WIS-MD-000010, Rev. 00, "Summary of Dissolved Concentration Limits" (F0095)

This model report exhibited traceability and transparency in describing how the solubility response surfaces or distributions were formulated. These response surfaces or distributions were directly used in the TSPA model where solubility is addressed. There is coordination among the "In-Package Chemistry," "In-Package Chemistry Summary Abstraction," and "Summary of Dissolved Concentration Limits" AMRs.

This AMR received an AP-2.14Q review and all comments were satisfactorily resolved; however, model validation was not adequately addressed in the approved/issued AMR. Based upon discussion during the audit, the author(s) has developed an acceptable approach for validating the model in the next Revision/ICN. Refer to DR LVMO-00-119 for issues regarding model validation.

ANL-NBS-MD-000005, Rev. 00, "Abstraction of Drift Seepage" (U0120)

This model report was consistent with the requirements of AP-3.10Q, and was well written. Input data to the model were obtained from field measurements and developed data from other AMRs. Confidence in the model results was discussed within a "model validation" section that compared abstraction model results with process model results. This AMR received an AP-2.14Q review at the personal request of the author. Note that the resolution of review comments resulted in strengthening the model validation section of the Rev. 00 report. Therefore, the deficient condition documented in DR LVMO-00-D-119 regarding model validation does not apply to this AMR.

Model assumptions were not mapped from the supporting AMRs into this document on a one-for-one basis; they were developed by the author and believed to be necessary and inclusive for the purposes of the model development.

In addition, alternative conceptual models for unsaturated fracture flow were not discussed nor listed in the model report; interested readers were directed through reference to other AMRs and publications for further information. Refer to DR LVMO-00-D-118 for issues regarding transparency of decisions related to uncertainty/variability values, assumptions and alternative conceptual models. Note that evaluation of model uncertainties depended on the selection of parameter distributions, which may be challenged on statistical grounds. (See Recommendation # 6).

ANL-NBS-MD-000007, Rev. 00, "Abstraction of BDCF Distribution for Irrigation Period" (B0075)

This analysis report was consistent with the requirements of AP-3.10Q, and was well written. This AMR did not receive an AP-2.14Q review, since it was developed by the PA organization for use by the PA organization. Input data to the analysis were obtained as developed data from other AMRs. Confidence building in the results of the Biosphere Dose Conversion Factors (BDCF) analysis was discussed. In addition, five technical acceptance criteria established in the NRC TSPAI were addressed within this document.

The application of assumptions was not a mapping from the supporting AMRs into this analysis on a one-for-one basis. Risk was not used to define the critical group for exposure; the alternative conceptual model of critical group using risk was not addressed. Refer to DR LVMO-00-D-118 for issues regarding transparency of decisions related to uncertainty/variability values, assumptions and alternative conceptual models. Note that evaluation of model uncertainties depended on the selection of parameter distributions, which may be challenged on statistical grounds (See Recommendation #6).

MDL-WIS-PA-000002, "Total System Performance Assessment (TSPA) Model for Site Recommendation (draft TSPA-SR model report)

This report was in draft (pre-checking/review) at the time of the audit; however, the audit team provided recommendations for enhancement during the audit. Errors regarding software version numbers and qualification status were identified, and recommendations were made to re-evaluate/reconsider the classification of software codes as routines. The approach to model validation (confidence building) based on validation of the lower level models was challenged during the audit. Because validation of the TSPA-SR model is perceived as extremely complex, an alternative validation method per AP-3.10Q, Revision 2, ICN 2, paragraph 5.3c, should be considered. The Phase 2 audit will focus on the completed Rev. 00 report and follow-up of technical recommendations made during the audit.

5.5 Summary of Deficiencies

5.5.1 Corrective Action Request (CAR)

None

5.5.2 Deficiency Reports (DR)

DR LVMO-00-D-117

AMR authors are not documenting the assessment of impact of TBV inputs on analysis and model documentation, nor are they documenting the impact and appropriateness of unqualified data on model validity, as required by AP-3.10Q. The DR recommends that this requirement be re-evaluated.

DR LVMO-00-D-118

The rational for exclusion (documentation of consideration) of uncertainty/variability values, assumptions, and alternative conceptual models contained in process-level AMRs is not clearly documented. Therefore, it is not transparent in the documentation whether these uncertainty/variability values, assumptions, and alternative conceptual models were considered while developing the abstraction-level AMRs that directly feed the TSPA-SR model. In addition, NRC IRSR criteria are not clearly identified and/or addressed within many AMRs that support the TSPA-SR.

DR LVMO-00-D-119

Model Validation (confidence building) is not in all cases documented in accordance with AP-3.10Q; i.e., validation criteria and methods, tests conducted, and results are not documented within several AMRs; nor is an alternative approach suggested when validation is impractical based on lack of available data to support validation.

DR LVMO-00-D-120

Required background information, e.g., software identification, name, version, revision, ID number and a listing of constraints, assumptions, and limitations, relating to data submitted to the TDMS Model Warehouse, is not always included with the model input/output data.

Therefore, this information is not entered into the TDMS Model Warehouse as specified in AP-SIII.3Q, "Submittal and Incorporation of Data to the Technical Data Management System," and AP-3.10Q.

DR LVMO-00-D-121

Planning documents for the WAPDEG abstraction AMR and the FEPs database were not followed and/or revised when substantive deviations from the plan were made. Specifically, the WAPDEG AMR did not address IRSR acceptance criteria or TSPA Peer Review Panel recommendations as indicated in the plan. Also, planning documents were not followed (or revised) to ensure the accuracy and completeness of the FEPs database (Supplement V) and secure the quality status of the FEPs database via qualification of the database software application per AP-SI.1Q, "Software Management" (Supplement I).

Note that follow-up to two previously identified deficiencies related to software was conducted during the audit:

DR LVMO-00-D-038

No additional instances of use of unqualified software codes without implementing requirements of AP-SI.1Q, Section 5.11, were identified. Section 5.11 establishes the requirements for use of software while in the process of being qualified. The audit results support closure of this DR.

DR LVMO-00-D-039

Although software routines are documented, there is no evidence in some AMRs that demonstrates that the algorithms/equations identified were calculated and proven by hand, i.e., without the use of computer-aided tools. Furthermore, it is questionable whether some of the designated routines can realistically be calculated by hand, as required by AP-SI.1Q; therefore, it is questionable whether these software codes meet the intended definition of a routine. The results of this audit do not support closure of this DR.

5.5.3 Deficiencies Corrected During the Audit (CDA)

None.

6.0 RECOMMENDATIONS

1. Due to the difficulty in remedying model validation issues, it is apparent that a more rigorous approach to model validation is needed. To ensure that validation criteria are established prior to completing the analysis or model, validation should be addressed within a planning document that is subject to review and approval by PA management.

2. The TSPA-SR Methods and Assumptions document should be revised to meet the NRC TSPAI, Rev. 2 acceptance criteria, and to replace the AMR to PMR to TSPA-SR model document hierarchy with the AMR to TSPA-SR model hierarchy.

3. AP-2.14 reviews appear to be performed at the process-level and not at the abstraction-level; therefore, it is perceived that the PA AMRs have received a less rigorous evaluation than supporting AMRs. Future AMR revisions/ICNs should receive this review, especially considering the importance of abstraction-level AMRs in the hierarchy of documents that support the TSPA-SR and the level of importance of AMRs that have been slated for revision based on project priorities. Consideration should be given to removing the AP-3.10Q section that allows AMR authors to avoid the AP-2.14Q review process.

4. The TSPA-VA peer review panel recommendations, which were formally responded to and included in planning documents related to the TSPA-SR, should be tracked and addressed in an organized manner within all future AMR revisions. The same applies to NRC IRSR acceptance criteria.

5. Assumptions are listed in AMRs, but not all assumptions receive TBV numbers. Clarification is needed regarding which assumptions should receive TBV numbers and which ones should not, and how assumptions should be treated and/or dispositioned when a formal tracking method has not been applied.

6. Uncertainty in parameter values, alternative conceptual models, and assumptions have often been addressed by the analysts through the use of conservatisms and/or statistical distributions with expanded standard deviations. It is recommended that PA management acquire the services of a recognized technical expert in statistics to review the extensive use of various statistical distributions in the development of process models, abstraction models, and the TSPA-SR model.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Andrews, Robert	M&O PAO Dept. Manager	X	X	X
Ashe, Ken	M&O Licensing Support Staff			X
Archuleta, Jose	M&O/SNL PAO Staff			X
Baca, Robert	M&O/SNL PAO Staff			X
Bailey, Jack	M&O Regulatory & Licensing Director			X
Belke, William	NRC On-Site Representative			X
Brady, Patrick	M&O/SNL PAO Staff		X	X
Brightman, Fifine	M&O/Technical Data Management Staff		X	
Brodsky, Nancy	M&O/SNL PAO Staff			X
Bullard, Bryan	M&O PAO Staff			X
Clark, James E.	OQA/Quality Systems		X	
Craig, Patricia	M&O Software Management Staff		X	
Dana, Steve	OQA Quality Engineering Lead		X	X
Dials, George	M&O General Manager			X
Freeze, Geoffrey	M&O/SNL PAO Staff		X	X
Graff, James	OQA/SNL Lab Staff			X
Harris-Womack, Sharon.	M&O Records Management		X	
Hasson, Robert	OQA/QATSS Audit Lead	X		X
Henderson, Lin	M&O PAO Staff	X		X
Ho, Cliff	M&O/SNL PAO Section Manager		X	X
Hodgson, Betty	M&O Software Management Staff		X	
Hodson, William	M&O Technical Data Management Manager		X	
Howard, Robert	M&O PAO Deputy Manager	X	X	X
Hunt, William	M&O Product Assurance Staff		X	
Jaeger, Michael	M&O Data/Software Quality Dept. Staff		X	
Jenkins, Daniel	M&O Data/Software Quality Dept. Staff		X	
Jolley, Darren	M&O PAO, Process Support Manager	X	X	X

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Keith, Dale	M&O Technical Data Management Staff		X	
Lee, Joon	M&O PAO Staff	X	X	X
Lee, Marco	M&O Product Assurance Staff		X	
Lohrke, Constance	M&O Product Assurance Staff		X	
Low, James	M&O Information Technology Manager			X
MacKinnon, Robert	M&O Information Technology Manager/SNL PAO Section Manager	X	X	X
Mattie, Patrick	M&O PAO Staff		X	
McDaniel, Mary	M&O Product Assurance Manager			X
McGrath, Michael	M&O Product Assurance Staff		X	
McNeish, Jerry	M&O PAO Section Manager	X	X	X
Mehta, Sunil	M&O PAO Staff			X
Mellington, Suzanne	DOE/AM Office of Project Execution			X
Miller, Steven	M&/SNL PAO Staff			X
Mon, Kevin	M&O PAO Staff			X
Monib, Ahmed	M&O PAO Staff			X
Nowak, James	M&/SNL PAO Staff			X
Palay, Christian	M&O Thermal & EBS Testing Staff			X
Pelletier, John	M&O SNL/Software Lead	X	X	X
Rechard, Rob	M&O/SNL PAO Staff		X	X
Replogle, James	DOE/Office of Project Execution			X
Richards, Robert	M&O/SNL PAO Staff			X
Rogers, Ralph	MTS Representative			X
Safley, L. Gene	M&O Technical Data Management Staff	X		X
Schenker, Albert	M&O/SNL PAO Staff	X		X
Sipe-Eaton, Gina	M&O Product Assurance Staff		X	
Smith, Anthony	M&O PAO Staff			X
Splawn, Stephen	M&O Software Management Section Manager		X	
Stambaugh, Roberta	M&O Licensing Support Staff			X
Swenning, Steven	OQA/Quality Systems Staff		X	X

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Swift, Peter	M&O/SNL PAO Deputy Manager			X
Tappen, Jeffrey	M&O Biosphere Analysis Section Staff		X	X
Tung, Chao-Hsiung	M&O Biosphere Analysis Section	X		
Wemheuer, Robert	M&O Data/Software Quality Dept. Manager			X
Wilson, Michael	M&O/SNL PAO Representative		X	X
Woods, Mary	M&O Product Assurance Represesentative		X	
Wright, Samantha	M&O Product Assurance Staff		X	
Younker, Jean	M&O Applied Research & Testing Director			X

ATTACHMENT 2

SUMMARY TABLE OF AUDIT RESULTS

Process Steps	Details (Checklist)	Deficiencies	Recommendations	Process Effectiveness	Overall
Overall Approach	Pgs. 1- 2	N/A	2	SAT	SAT
Acceptance Criteria	Pgs. 3 - 4	N/A	2	SAT	SAT
Milestones	Pgs. 4 - 5	N/A	N/A	SAT	SAT
Planning	Pgs. 6 - 8	LVMO-00-D-121	1	UNSAT	UNSAT
Impact Evaluations	Pgs. 9 - 10	N/A	N/A	IND *	IND *
Technical Review	Pgs. 11 - 14	N/A	3	SAT	SAT
NRC KTI Issues/Subissue Status	Pgs. 15 - 17	LVMO-00-D-118	4	UNSAT	UNSAT
Peer Review Panel Follow-up	Pg. 18	LVMO-00-D-118	4	UNSAT	UNSAT
Repository Safety Strategy	Pgs. 19 - 20	N/A	N/A	SAT	SAT
Input Requests	Pgs. 21 - 23	N/A	N/A	SAT	SAT
Data Qualification/Acceptance/ Status	Pgs. 24 - 28	LVMO-00-D-117 LVMO-00-D-120	N/A	IND**	IND **
Expert Judgment/Elicitation	Pg. 29	N/A	N/A	SAT	SAT
Assumptions	Pg. 30	LVMO-00-D-118	5	UNSAT	UNSAT
Software Qualification	Pgs. 31 - 45	LVMO-00-D-038 LVMO-00-D-039	N/A	SAT	UNSAT***
FEPs Process	Pgs. 46 - 57	N/A	N/A	IND *	IND *
Develop Models	Pgs. 58 - 121	LVMO-00-D-117 LVMO-00-D-118 LVMO-00-D-119	N/A	UNSAT	UNSAT
Estimate Parameter Ranges and Uncertainty	Pgs. 58 -121	LVMO-00-D-118	6	IND *	IND *
Perform Calculations	N/A	N/A	N/A	IND *	IND *
Interpret/Document Results	Pgs. 58 - 121	LVMO-00-D-118	N/A	IND *	IND *
Comparisons with Regulatory Requirements	N/A	N/A	4	IND *	IND *
Quantification of Output Uncertainty	N/A	N/A	N/A	IND *	IND *

Legend

SAT - Satisfactory
UNSAT - Unsatisfactory
IND - Indeterminate
N/A - Not Applicable

* IND designation is based on further evaluation required during the OQA TSPA-SR Phase 2 audit.

** IND designation is based upon uncertainty regarding when/if TBV status will be cleared for data used in the TSPA-SR.

*** Based on follow-up to previously issued DR.